

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,	)	
	)	
Plaintiff and	)	
Counterclaim Defendant,	)	
	)	
v.	)	C.A. No. 07-229 (GMS)
	)	
RANBAXY INC., and RANBAXY	)	
LABORATORIES LIMITED,	)	
	)	
Defendants and	)	
Counterclaim Plaintiffs.	)	
	)	

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**PLAINTIFF'S REPLY TO COUNTERCLAIMS OF DEFENDANTS  
RANBAXY INC. AND RANBAXY LABORATORIES LIMITED**

Plaintiff and Counterclaim-Defendant Merck & Co., Inc. ("Merck") hereby replies to the Answer and Counterclaims of Defendants and Counterclaim-Plaintiffs Ranbaxy Inc. and Ranbaxy Laboratories Limited (collectively, "Ranbaxy") as follows:

**PARTIES, JURISDICTION AND VENUE**

41. Merck admits the allegations in paragraph 41 of Ranbaxy's Answers and Counterclaims ("Ranbaxy's Counterclaims").

42. Merck admits the allegations in paragraph 42 of Ranbaxy's Counterclaims.

43. Paragraph 43 of Ranbaxy's Counterclaims states legal conclusions to which no response is required.

44. Merck admits that it has submitted itself to the personal jurisdiction of this Court for the purposes of this action.

45. Merck admits that venue is proper in this district pursuant to 28 U.S.C. §§ 1391(c) and (d) and 1400(b) for the purposes of this action.

### **THE CONTROVERSY**

46. Merck admits that this is an action based on an actual controversy between Ranbaxy and Merck concerning at least in part the validity of U.S. Patent No. 5,147,868 ("the '868 patent"), whether Ranbaxy infringed the '868 patent by filing its ANDA, whether Ranbaxy's proposed injectable products described in its ANDA ("Ranbaxy's proposed ANDA products") will infringe the '868 patent, whether the FDA should be ordered not to approve Ranbaxy's ANDA until after the '868 patent has expired and whether Ranbaxy should be enjoined from manufacturing, using, selling, offering to sell, or importing into the United States Ranbaxy's proposed ANDA products before the '868 patent expires. Merck denies the remaining allegations in paragraph 46 of Ranbaxy's Counterclaims.

47. Merck admits the allegations in paragraph 47 of Ranbaxy's Counterclaims.

48. Merck admits that it has alleged that the claims of the '868 patent cover, *inter alia*, the compounds cilastatin and cilastatin sodium and that it alleged in its complaint that it currently sells PRIMAXIN® I.M., which is an injectable suspension containing imipenem and cilastatin sodium, and PRIMAXIN® I.V., which is an injection containing imipenem and cilastatin sodium. Merck denies the remaining allegations in paragraph 48 of Ranbaxy's Counterclaims.

49. Merck admits that it alleges that Ranbaxy's manufacture, use, sale or offer for sale of Ranbaxy's proposed ANDA products in the United States or importation of Ranbaxy's proposed ANDA products into the United States will constitute patent infringement

under 35 U.S.C. § 271 (a), (b) or (c). Merck also admits that it alleges that Ranbaxy's filing of an ANDA under Section 505(j) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 355(j), for a drug claimed in the '868 patent infringed the '868 patent under 35 U.S.C. § 271(e)(2). Merck admits, based on Ranbaxy's representations, that Ranbaxy has submitted, and is continuing to seek FDA approval of, an ANDA directed to products containing imipenem and cilastatin sodium, and is continuing to seek approval to engage in the commercial manufacture, use, offer for sale, sale, and importation into the United States of Ranbaxy's proposed ANDA products. Merck denies the remaining allegations of paragraph 49 of Ranbaxy's Counterclaims.

50. Merck admits the allegations in paragraph 50 of Ranbaxy's Counterclaims.

51. Merck admits the allegations in paragraph 51 of Ranbaxy's Counterclaims.

52. Merck admits, based on Ranbaxy's representations, that Ranbaxy has undertaken substantial efforts to develop and seek approval for its proposed imipenem and cilastatin ANDA products.

53. Merck admits that an actual justiciable controversy exists at least in part by virtue of Ranbaxy's notification to Merck of its ANDA filing, Ranbaxy's request for a covenant by Merck not to be sued on the '868 patent and Merck's subsequent filing of the present suit as to Ranbaxy's right to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, sale and importation into the United States of Ranbaxy's proposed ANDA products. Merck denies the remaining allegations in paragraph 53 of Ranbaxy's Counterclaims.

**COUNTERCLAIM I**  
(Noninfringement of '868 Patent)

54. Merck restates and incorporates by reference its responses to paragraphs 41-53 of Ranbaxy's Counterclaims as if fully set forth herein.

55. Merck is without sufficient knowledge or information to form a belief as to whether Ranbaxy has not at the present time already manufactured, used, sold, or offered for sale in the United States, or imported into the United States, any products that infringe any claim of the '868 patent, either literally or under the doctrine of equivalents, and on that basis denies those allegations. Merck denies that the manufacture, use, sale or offer for sale in the United States, or importation into the United States, of Ranbaxy's proposed ANDA products would not infringe any claim of the '868 patent. Merck further denies the remaining allegations in paragraph 55 of Ranbaxy's Counterclaims.

56. Merck denies the allegations in paragraph 56 of Ranbaxy's Counterclaims.

57. Merck denies the allegations in paragraph 57 of Ranbaxy's Counterclaims.

**COUNTERCLAIM II**  
(Invalidity of '868 Patent)

58. Merck restates and incorporates by reference its responses to paragraphs 41-57 of Ranbaxy's Counterclaims as if fully set forth herein.

59. Merck denies the allegations in paragraph 59 of Ranbaxy's Counterclaims.

60. Merck denies the allegations in paragraph 60 of Ranbaxy's Counterclaims.

**COUNTERCLAIM III**  
(Unenforceability)

61. Merck restates and incorporates by reference its responses to paragraphs 41-60 of Ranbaxy's Counterclaims as if fully set forth herein.

62. Merck denies the allegations in paragraph 62 of Ranbaxy's Counterclaims.

**RANBAXY'S DEMAND FOR JUDGMENT**

Merck denies that Ranbaxy is entitled to any aspect of the judgment it seeks.

**ADDITIONAL PRAYER FOR RELIEF**

WHEREFORE, in addition to its Complaint and in response to Ranbaxy's Counterclaims, Merck respectfully requests that:

- a. Judgment be entered declaring that each of the claims of the '868 patent is valid, enforceable and infringed;
- b. Judgment be entered that each of the counterclaims against Merck is dismissed with prejudice;
- c. Judgment be entered awarding Merck its costs and reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and
- d. The Court enter such other and further relief as the Court may deem just and proper under the circumstances.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Mary B. Graham*

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Dated: July 11, 2007  
952587

**CERTIFICATE OF SERVICE**

I hereby certify that on July 11, 2007, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

Frederick L. Cottrell , III, Esquire  
RICHARDS, LAYTON & FINGER, P.A.

Kelly E. Farnan, Esquire  
RICHARDS, LAYTON & FINGER, P.A.

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on July 11, 2007 upon the following individuals in the manner indicated:

**BY EMAIL AND HAND DELIVERY**

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